APR 18 2014

510(K) Summary

I. SUBMITTER NAME & ADDRESSS: Medtronic Sofamor Danek USA, Inc.
1800 Pyramid Place
Memphis, Tennessee 38132
Telephone: (901) 396-3133
Fax: (901) 346-9738
Establishment Registration: 1030489

CONTACT PERSON: Kelly Anglin
Senior Regulatory Affairs Specialist

DATE PREPARED: April 02, 2014

II. PROPOSED PROPRIETARY TRADE NAME:
MASTERGRAFT® Strip
MASTERGRAFT® Putty

DEVICE CLASSIFICATION NAME: Resorbable Calcium Salt Bone Void Filler

REGULATION NUMBER: 21 CFR 888.3045

CLASSIFICATION PRODUCT CODE: MQV

CLASS: II

III. IDENTIFICATION OF LEGALLY MARKETED DEVICES:

Table 1. Legally Marketed Devices

Device name	510(k) number	Substantial Equivalence date
MASTERGRAFT® Strip	K082166	06/02/2009
MASTERGRAFT® Putty	K071813	11/09/2007

IV. DEVICE DESCRIPTION:

MASTERGRAFT® STRIP

MASTERGRAFT® Strip is made from a combination of medical grade purified collagen and biphasic calcium phosphate ceramic. In the MASTERGRAFT® Strip device, the collagen is a highly purified (>95%) Type I bioresorbable lyophilized collagen. The biphasic ceramic portion of all devices is provided in a 15% hydroxyapatite and 85% β-tricalcium phosphate formulation. MASTERGRAFT® Strip is supplied sterile in a premixed strip form for single patient use.

MASTERGRAFT® Strip is a biocompatible, osteoconductive, porous implant that allows for bony ingrowth across the graft site while resorbing at a rate consistent with bone healing. The device readily absorbs bone marrow aspirate and has been shown to heal bone defects.

MASTERGRAFT® Putty

MASTERGRAFT® Putty is made from a combination of medical grade purified collagen of bovine origin and biphasic calcium phosphate ceramic. The collagen component in the MASTERGRAFT® Putty device is Type I bovine collagen. The biphasic ceramic portion of MASTERGRAFT® Putty is provided in a 15 percent hydroxyapatite and 85 percent β-tricalcium phosphate formulation. MASTERGRAFT® Putty is supplied as a sterile, dry, solid, construct hydrated for single patient use and is a moldable form of bone void filler. MASTERGRAFT® Putty is a osteoconductive, porous implant that allows for bony ingrowth across the graft site while resorbing at a rate consistent with bone healing. MASTERGRAFT® Putty is biocompatible. MASTERGRAFT® Putty readily absorbs bone marrow aspirate and has been shown to heal bone defects.

The purpose of this Change Being Effected 510(k) is the addition of a new contraindication to the Instructions for Use (IFU) for the MASTERGRAFT® Strip and MASTERGRAFT® Putty devices.

V. INDICATIONS FOR USE:

MASTERGRAFT® Strip

MASTERGRAFT® Strip is to be combined with autogenous bone marrow and is indicated for bony voids or gaps that are not intrinsic to the stability of the bony structure; MASTERGRAFT® Strip can also be used with autograft as a bone graft extender.

The device is to be gently packed into bony voids or gaps of the skeletal system (i.e.,the posterolateral spine, pelvis, ilium, and/or extremities). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. The device resorbs and is replaced with bone during the healing process.

MASTERGRAFT® PUTTY

MASTERGRAFT® Putty combined with either autogenous bone marrow, and/or sterile water, and/or autograft is indicated as a bone void filler for bony voids or gaps that are not intrinsic to the stability of the bony structure. Additionally, MASTERGRAFT® Putty can be used with autograft as a bone graft extender. MASTERGRAFT® Putty is to be gently packed into bony voids or gaps of the skeletal system (e.g., the posterolateral spine, pelvis, ilium, and/or extremities). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. MASTERGRAFT® Putty resorbs and is replaced with bone during the healing process.

VI. SUMMARY OF THE TECHNOLOGICAL CHARACTERISTICS:

Table 2. Summary of the technological Characteristics		
Comparison Feature	**Subject** **MASTERGRAFT® Strip** **K082166 S.E. 06/02/2009**	**Predicate MASTERGRAFT® Strip**
Indication for Use	Identical	K082166 S.E. 06/02/2009
Fundamental Scientific Technology • Operating Principle • Mechanism of Action	Identical	K082166 S.E. 06/02/2009
Basic Design	Identical	K082166 S.E. 06/02/2009
Performance	Identical	K082166 S.E. 06/02/2009
Sterilization	Identical	K082166 S.E. 06/02/2009
Shelf-Life	Identical	K082166 S.E. 06/02/2009
Packaging	Identical	K082166 S.E. 06/02/2009
Use of rigid fixation	Identical	K082166 S.E. 06/02/2009
Safety and Effectiveness profile	Identical	K082166 S.E. 06/02/2009

Table 3. Summary of the technological Characteristics		
Comparison Feature	**Subject** **MASTERGRAFT® Putty** **K071813 S.E. 11/09/2007**	**Predicate MASTERGRAFT® Putty**
Indication for Use	Identical	K071813 S.E. 11/09/2007
Fundamental Scientific Technology • Operating Principle • Mechanism of Action	Identical	K071813 S.E. 11/09/2007
Basic Design	Identical	K071813 S.E. 11/09/2007
Performance	Identical	K071813 S.E. 11/09/2007
Sterilization	Identical	K071813 S.E. 11/09/2007
Shelf-Life	Identical	K071813 S.E. 11/09/2007
Packaging	Identical	K071813 S.E. 11/09/2007
Use of rigid fixation	Identical	K071813 S.E. 11/09/2007
Safety and Effectiveness profile	Identical	K071813 S.E. 11/09/2007

VII. DISCUSSION OF NON-CLINICAL TESTING:

Non-clinical testing was performed in support of substantial equivalence for the cited predicates K082166 and K071813 in accordance with FDA Recognized Consensus Standards and FDA Guidelines, where applicable. No new non-clinical testing was performed or submitted in support of this 510(k).

Table 4. Non-clinical testing

Cleared Device	Animal Model	Study Purpose	Substantial Equivalence
MASTERGRAFT® Strip	Ovine Femoral Defect Model	In-vivo performance comparison	MASTERGRAFT® Matrix (K023553 S.E. 04/22/2003)
	Rabbit Lumbar Intertransverse Process Fusion Model	Fusion results MASTERGRAFT® Strip + autograft as bone graft extender compared to autograft fusion results	Equivalent to autograft fusion results
MASTERGRAFT® Putty	Ovine Cortico-cancellous Defect Model	In-vivo performance comparison	HEALOS® Bone Graft Material (K012751 S.E. 11/14/2001)
	Rabbit Lumbar Intertransverse Process Fusion Model	Fusion results MASTERGRAFT® Putty + autograft as bone graft extender compared to autograft fusion results	Equivalent to autograft fusion results

VIII. CONCLUSION:

Documentation provided in this submission demonstrates that the subject devices are substantially equivalent to the previously cleared MASTERGRAFT® Strip (K082166 S.E. 06/02/2009) and MASTERGRAFT® Putty (K071813 S.E. 11/09/2007) devices. The

subject devices are substantially equivalent to predicates in several categories including: indication, material components, sterility, shelf-life, and biocompatibility.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

April 18, 2014

Medtronic Sofamor Danek USA, Inc.
Ms. Kelly Anglin
Senior Regulatory Affairs Specialist
1800 Pyramid Place
Memphis, Tennessee 38132

Re: K140375
Trade/Device Name: MASTERGRAFT® Strip; MASTERGRAFT® Putty
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: Class II
Product Code: MQV
Dated: February 13, 2014
Received: February 14, 2014

Dear Ms. Anglin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K140375

Device Name: MASTERGRAFT® Strip

INDICATIONS FOR USE:

MASTERGRAFT® Strip is to be combined with autogenous bone marrow and is indicated for bony voids or gaps that are not intrinsic to the stability of the bony structure and can be used as a bone graft extender.

The device is to be gently packed into bony voids or gaps of the skeletal system (i.e.. the posterolateral spine, pelvis, ilium, and/or extremities). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. The device resorbs and is replaced with bone during the healing process.

Prescription Use __X___ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Laurence D. Coyne -S

(Division Sign-Off)
Division of Orthopedic Devices
510(k) Number: K140375

510(k) Number (if known): K140375

Device Name: MASTERGRAFT® Putty

INDICATIONS FOR USE:

MASTERGRAFT® Putty combined with either autogenous bone marrow, and/or sterile water, and/or autograft is indicated as a bone void filler for bony voids or gaps that are not intrinsic to the stability of the bony structure. Additionally, MASTERGRAFT® Putty can be used with autograft as a bone graft extender. MASTERGRAFT® Putty is to be gently packed into bony voids or gaps of the skeletal system (e.g., the posterolateral spine, pelvis, ilium, and/or extremities). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. MASTERGRAFT® Putty resorbs and is replaced with bone during the healing process.

Prescription Use __X___ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Laurence D. Coyne -S

(Division Sign-Off)
Division of Orthopedic Devices
510(k) Number: K140375